No. 15-274

In The
Supreme Court of the United States

WHOLE WOMAN'S HEALTH, et al.,

Petitioners,

v.

JOHN HELLERSTEDT, M.D., Commissioner of the Texas Department of State Health Services, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

AMICUS CURIAE BRIEF OF FORMER ABORTION PROVIDERS; POST-ABORTIVE WOMEN AND THEIR FAMILIES; NATIONAL ASSOCIATION OF PROLIFE NURSES; AND NATIONAL ASSOCIATION OF CATHOLIC NURSES, U.S.A. IN SUPPORT OF RESPONDENTS

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CORPORATE DISCLOSURE STATEMENT

Amici National Association of Prolife Nurses and National Association of Catholic Nurses, U.S.A. are nongovernmental corporate entities, and they have no parent corporations and no publicly held corporations hold 10 percent or more of their stock.

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STATEMENT OF INTEREST OF AMICI CURIAE

Both parties have given consent to file this amicus curiae brief. Counsel for Amici has prepared this brief supporting Respondents.[1]

Post-abortive women and their families understand the need for health and safety laws for women considering an abortion and believe H.B. 2 is important to protect women. The post-abortive women are Yvonne Brewer (Idaho); Tina Brock (Georgia); Cynthia Carney (Oklahoma); Toni Cordell (North Carolina); Brandi Dudley (Texas); Debby Efurd (Texas); Carol Everett (Texas); Sherri Hayden (Texas); Dr. Alveda King, niece of Dr. Martin Luther King (Georgia); Tammy Holly (Michigan); Shelly Lee (Texas); Kay Painter (Idaho); Susan Potter (Georgia); Kathy Rutledge (Kentucky); Threesa Sadler (Texas); Caron Strong (California); Luana Stoltenberg (Iowa); Sue Swander (Oregon); Paula Talley (Arkansas); Julie Thomas (Georgia); Deborah Tilden (Oregon); Cindy

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[1] The parties were notified ten days prior to the due date of this brief of the intention to file. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. Trinity Legal Center is a nonprofit corporation and is supported through private contributions of donors who have made the preparation and submission of this brief possible. No person other than amici curiae, their counsel, or donors to Trinity Legal Center made a monetary contribution to its preparation or submission. The parties have consented to this brief.

Williamson (Tennessee); Leslie Wolbert (North Carolina); Ann Younger (Texas); Joyce Zounis (Colorado).

Eileen Smith's daughter Laura died following a surgical abortion in Massachusetts. Monty Patterson's daughter Holly died following a medical abortion in California.

Former abortion providers include Carol Everett (Texas); Dr. Noreen Johnson (Texas); Dr. Anthony Levatino (New Mexico); and, Dr. Haywood Robinson (Texas).

The National Association of Prolife Nurses was chartered in 1978 as a not-for-profit organization. Some members of the organization have exposed health and safety practices at abortion facilities that they have witnessed. The National Association of Catholic Nurses, U.S.A. dates back to the 1930's and is a 501(c)(3) non-profit organization. Both organizations are long-standing groups dedicated to the highest ethical medical standards. They have a deep interest in ensuring women have good medical care and that they know the physical risks of abortion based on what they have experienced and the extensive reliable scientific data. Amici have members across the United States, including in Texas.

SUMMARY OF THE ARGUMENT

I.

Medical abortions such as the RU-486 regimen have dangerous complications and can cause death.

The Federal Drug Administration (FDA) and the drug manufacturer have warned of complications and the risk of death. In addition, the RU-486 regimen has a high failure rate which requires further surgical procedures. Hospitalizations, blood transfusions, and infections are among the adverse complications which require the ongoing care of a woman's physician. Therefore, H.B. 2 provides for the health and safety of women and should be upheld.

II.

Surgical abortions also have substantial physical health risks including the risk of death. H.B. 2 provides common sense health and safety regulations to protect women just as any other surgical out-patients have. Ambulatory surgical centers have monitoring and emergency equipment that can save a woman's life when complications arise. Doctors having privileges prevents itinerant abortionists by providing continuity of care when complications occur. In addition, having hospital privileges supports this Court's assumption in *Roe* of a normal doctor-patient relationship. Therefore, the Court of Appeals' decision should be affirmed.

III.

This Court has long recognized that legislatures should be given broad deference in their findings and enactments. Because health issues are complex factual medical issues that involve policy, they are

best left to the legislative branch of government. The Texas Legislature has provided for health and safety measures to protect women within this Court's established guidelines and tests. This is a legitimate and constitutional exercise of the State's interest in protecting women, and therefore, H.B. 2 should be upheld.

ARGUMENT

I. MEDICAL ABORTIONS HAVE DANGEROUS AND FATAL PHYSICAL COMPLICATIONS, AND THEREFORE, TEXAS IS JUSTIFIED IN PROVIDING SAFETY MEASURES TO PROTECT WOMEN.

Medical abortions such as the RU-486 regimen pose a substantial risk to the physical health of women including severe complications and the risk of death. The scientific studies demonstrate a substantially higher risk of death from infection than surgical abortions or childbirth. There is also a high failure rate of the drug requiring additional surgeries and medical care. Therefore, the protections of H.B. 2 are necessary to protect women.

A. H.B. 2 Is Necessary Because of the Documented Physical Risks and Fatal Complications of Medical Abortions.

Both the FDA[2] and Danco, the drug manufacturer,[3] have acknowledged that RU-486 poses health risks for women. The Mifeprex drug label acknowledges that "[n]early all of the women who receive Mifeprex and misoprostol [the RU-486 regimen] will report adverse reactions, and many can be expected to report more than one such reaction."[4]

The Congressional Staff Report on RU-486 cited FDA findings concerning the physical risks to women taking the RU-486 regimen.[5] These included: "abdominal pain; uterine cramping; nausea; headache;

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[2] Congressional Staff Report, *The FDA and RU-486: Lowering the Standard for Women's Health*, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, at page 30 (Oct. 2006), *archived at* http://old.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf (*citing* FDA findings and reporting adverse reactions).

[3] *See* Danco's MIFEPREX™ Label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm (last visited Jan. 14, 2016).

[4] *Id.* (stating adverse reactions include abdominal pain, uterine cramping, nausea, vomiting, diarrhea, pelvic pain, fainting, headache, dizziness, and asthenia).

[5] Congressional Staff Report, *The FDA and RU-486: Lowering the Standard for Women's Health*, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, at page 30 (Oct. 2006), *archived at* http://old.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf.

vomiting; diarrhea; dizziness; fatigue; back pain; uterine hemorrhage; fever; viral infections; vaginitis; rigors (chills/shaking); dyspepsia; insomnia; asthenia; leg pain; anxiety; anemia; leucorrhea; sinusitis; syncope; endrometritis/salpingitis/pelvic inflammatory disease; decrease in hemoglobin greater than 2 g/dL; pelvic pain; and fainting."[6]

Furthermore, the FDA's Medical Officer's review indicated that, "[m]ore than one adverse event was reported for most patients. Approximately 23% of the adverse events in each gestational age group were judged to be severe."[7] The Congressional Staff Report calls these "startling adverse effects."[8]

The Report also expressed concern about "the incredibly high failure rate of the drug."[9] The FDA knew the failure rate was averaging 14.6% in the U.S. trial testing of the drug through 63 days gestation. The findings were that 27% had ongoing pregnancies, 43% had incomplete abortions, 10% requested and had surgical terminations, and the remaining 20% of patients had surgical terminations performed because of medical indications directly related to the medical procedure.[10]

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[6] *Id.*

[7] *Id.*

[8] *Id.* (stating these startling adverse effects were known by the FDA during the RU-486 NDA review process).

[9] *Id.*

[10] *Id.*

The Congressional Staff Report stated the "best" outcome was where the pregnancies were less than or equal to 49 days, but there was still a 7.9% failure rate of RU-486 requiring surgical intervention.[11] The Report warned that as "the gestational age increases, the failure rate of RU-486 increases rapidly."[12] This is why the "off label" use for increased gestational age of RU-486 was not approved. The Report surmised that: "By any objective standard, a failure rate approaching eight percent and requiring subsequent surgical intervention as the 'best' outcome is a dismal result."[13]

Therefore, the Congressional Staff Report concluded that: "The integrity of the FDA in the approval and monitoring of RU-486 has been substandard and necessitates the withdrawal of this dangerous and fatal product before more women suffer the known and anticipated consequences or fatalities."[14] It further concluded: "RU-486 is a hazardous drug for women, its unusual approval demonstrates a lower standard of care for women, and its withdrawal from the market is justified and necessary to protect the public's health."[15]

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[11] *Id.*

[12] *Id.* (stating increased to "17% in the 50-56 days gestation group, and 23% in the 57-63 days gestation group").

[13] *Id.*

[14] *Id.* at 40.

[15] *Id.*

In 2011, the FDA issued a report on the post-marketing events of RU-486.[16] The FDA reported that there were 2,207 adverse events (complications) in the United States related to the use of RU-486, including hemorrhaging, blood loss requiring transfusions, serious infections, and death.[17] Among the 2,207 adverse events were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections").[18]

In its 2015 pronouncement concerning RU-486, the FDA warned about sepsis infection and recommended that "healthcare practitioners have a high index of suspicion for serious infection and sepsis."[19] Women who have taken RU-486 and "develop stomach pain or discomfort, or have weakness, nausea, vomiting or diarrhea with or without fever" may have an indication that sepsis is present.[20] Because sepsis is a potentially life-threatening complication and can damage organs and cause them to fail, the

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[16] Food and Drug Administration, *Mifepristone U.S. Post-marketing Adverse Events Summary Through 04/30/2011* (July 2011), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf (last visited Jan. 14, 2016).

[17] *Id.*

[18] *Id.*

[19] Food and Drug Administration, *Mifeprex (mifepristone) Information* (07/17/2015), *available at* http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm (last visited Jan. 14, 2016).

[20] *Id.*

FDA warns that "immediate treatment with antibiotics that includes coverage of anaerobic bacteria such as *Clostridium sordellii*" should be initiated.[21]

In analyzing the scientific literature, medical researchers have concluded that there are increased physical risks with the RU-486 regimen.[22] They also report that: "Mifepristone abortion has 10 times more risk of death from infection than surgical abortion and 50 times more risk of death from infection compared to childbirth."[23]

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[21] *Id.*

[22] Shuping, Harrison, Gacek, *Medical Abortion with Mifepristone (RU-486) Compared to Surgical Abortion* (Apr. 16, 2007), *available at* http://www.lifeissues.net/writers/shu/shu_06mifepristone_ru486.html (last visited Jan. 23, 2016).

[23] *Id.* (citations omitted).

The protections provided in H.B. 2 are necessary and important to protect women when these severe complications occur. Abortionists need hospital privileges for access to emergency care when there are physical complications.[24] Women must have truthful and accurate information about the risks and understand that emergency treatment may be needed and know how to access it.[25] Continuity of care is important for both the current and future pregnancies.

B. The Real Life Experiences of Women Demonstrate the Dangers of Medical Abortions Which Require Ongoing Medical Treatment.

A significant percentage of women have had medical abortions. Approximately 1.2 million abortions are performed each year in the United States.[26] Of that number, 17% of all abortions are medical abortions.[27] For pregnancies within the first nine weeks, that percentage rises to one-quarter of the

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[24] *See* Affidavit of Dr. Mayra Thompson, Appendix C.

[25] *Id.*

[26] Guttmacher Institute, *Fact Sheet: Facts on Induced Abortions in the United States* (Aug. 2011), *available at* http://www.guttmacher.org/pubs/fb_induced_abortion.html (last visited Jan. 14, 2016).

[27] *Id.*

abortions are medical abortions.[28] Therefore, approximately 200,000 women are at risk each year for physical harm from medical abortions such as the RU-486 regimen. This number will continue to grow as the use of RU-486 is on the rise.[29] Thus, women are entitled to the safety measures of H.B. 2 in providing for ambulatory surgical centers where doctors are in close proximity and there is an ongoing doctor-patient relationship for the continuity of her care.

Amicus Monty Patterson understands the physical health risks of medical abortions (RU-486) including the risk of death. His daughter Holly was seventeen years old when she discovered she was seven-weeks pregnant.[30] On September 10, 2003, Holly went to a Planned Parenthood clinic to terminate her pregnancy with a medical abortion.[31]

On September 13, Holly repeatedly called the Planned Parenthood clinic hotline and complained of

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[28] *Id.*

[29] Stein, *As Abortion Rate Drops, Use of RU-486 Is on Rise*, Washington Post (Jan. 22, 2008), *available at* http://www.washingtonpost.com/wp-dyn/content/article/2008/01/21/AR2008012102075.html (last visited Jan. 23, 2016) (RU-486-induced abortions have been rising by 22 percent a year).

[30] Abortion Pill Risks: Just the Facts, *Holly Patterson's Story*, *available at* http://abortionpillrisks.org/real-stories/hollys-story/ (last visited on Jan. 14, 2016).

[31] *Id.*

severe cramping.[32] She was told her symptoms were normal and simply to take the clinic prescribed Tylenol-Codeine painkiller.[33] After calling the clinic's hotline again, she was told to go to a local hospital's emergency room if the pain continued.[34]

By September 14, Holly went to the emergency room because she was still experiencing extreme cramping and bleeding.[35] Although the doctor there was told about her abortion, he sent her home after an injection of narcotics and yet more painkillers.[36] The severity of the pain continued and Holly was weak, vomiting, and unable to walk.[37] On September 17, she was re-admitted to the hospital where she died later that afternoon.[38]

On October 31, 2003, the Alameda, California coroner's office issued a report concluding that Holly Patterson died from septic shock, due to endomy ometritis (uterus related blood infection), due to a therapeutic, drug-induced abortion.[39] Although Holly's

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[32] *Id.*

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] *Id.*

was the first death in the United States after taking RU-486, unfortunately, other women have also died.[40]

Medical abortions pose significant physical risks including death, and therefore, H.B. 2 enacted reasonable protections for women by providing a qualified doctor who can give continuity of care. Providing for the safety of drugs and medical procedures are within the legitimate function of the State,[41] and therefore, H.B. 2 is constitutional.

II. WOMEN CONSIDERING A SURGICAL ABORTION DESERVE THE SAME SAFETY PROTECTIONS AS ANY OTHER PERSON HAVING AN OUT-PATIENT SURGERY.

It is well documented that there are risks and complications of surgical abortions. Therefore, the State of Texas has a legitimate and constitutional right to protect women.

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[40] *Id.* (*citing* reports of women who have died after taking the RU-486 regimen).

[41] Planned Parenthood v. Casey, 505 U.S. 833 (1992) (recognizing that "[a]s with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion"). *Id.* at 878.

A. The Protections of H.B. 2 Are Justified Because Surgical Abortions Pose Risks of Significant Physical Complications.

There are a variety of physical complications that can occur with an abortion.[42] Some of the immediate physical complications include cervical injuries and perforated uterus, acute or chronic pain, organ or system failures cerebrovascular diseases, circulatory diseases, disseminated intravascular coagulation, amniotic fluid embolism, pulmonary embolism, and adult respiratory distress syndrome, various infections such as septic abortion, acute renal failure from septic abortion, autoimmune disease, endometritis, genital tract infection, pelvic inflammatory disease, and bacterial vaginosis.[43]

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[42] Thomas W. Strahan Memorial Library, *Physical Effects of Abortion*, *available at* http://abortionrisks.org/index.php?title=Physical_Effects_of_Abortion#Cervical_Injuries (last visited Jan. 14, 2016).

[43] Affidavit of Dr. Mayra Thompson at Appendix C. There is also a negative impact on later pregnancies such as infertility, ectopic pregnancy, placenta previa, subsequent miscarriages, premature birth, or low birth weight, and various cancer risks such as breast cancer. *Id.* *See generally* Thomas W. Strahan Memorial Library, *Physical Effects of Abortion*, *available at* http://abortionrisks.org/index.php?title=Physical_Effects_of_Abortion#Cervical_Injuries (last visited Jan. 14, 2016) (confirming both immediate complications and the negative impact on later pregnancies).

The risk of physical complications can occur at any stage of pregnancy,[44] and therefore, the protections provided in H.B. 2 are necessary for a woman's health. Based on the reliable scientific evidence, however, the physical risks are fewer the earlier a woman is in her pregnancy.[45] The Texas Woman's Right to Know Booklet warns:

> The risks are fewer when an abortion is done in the early weeks of pregnancy. The further along in the pregnancy, the greater the chance of serious complications and the greater the risk of dying from the abortion procedure.[46]

Mortality rates are significantly greater the later the abortion.[47] This is confirmed by record linkage studies in Finland, Denmark, and the United States

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[44] *See* Reardon & Coleman, *Short and Long Term Mortality Rates Associated with First Pregnancy Outcome: Population Register Based Study for Denmark 1980-2004*, 18(9) MED. SCI. MONITOR 71-76 (Aug. 2012), *available at* http://www.medscimonit.com/fulltxt.php?ICID=883338; *see also* Affidavit of Dr. Mayra Thompson at Appendix C.

[45] Tex. Dep't of Health, *A Woman's Right to Know Booklet*, *available at* https://www.dshs.state.tx.us/wrtk/default.shtm (last visited Jan. 14, 2016) (produced by the Dep't of Health after extensive hearings by the medical board and based on the scientific evidence).

[46] *Id.*

[47] *Id.* The booklet states that there is one death per every 530,000 abortions if you are at 8 weeks or less; one death per 17,000 abortions for pregnancies at 16–20 weeks; and one death per 6,000 abortions at 21 weeks and more.

which clearly demonstrate that abortion is associated with significantly higher mortality rates.[48] Furthermore, the reliable scientific evidence demonstrates that "each additional abortion is associated with an even higher death rate."[49] Texas' goal to protect women's health is constitutional because it is based on reliable scientific evidence and the legitimate interest of the State.

In *Roe*, this Court acknowledged the state's right to regulate abortion to protect women's health when the risk of death associated with abortion is greater than the risk of death associated with childbirth.[50] In 1973, the *Roe* Court believed that the risk of death associated with abortion was after the first

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[48] *See, e.g.*, Reardon & Coleman, *Short and Long Term Mortality Rates Associated with First Pregnancy Outcome: Population Register Based Study for Denmark 1980-2004*, 18(9) MED. SCI. MONITOR 71-76 (Aug. 2012), *available at* http://www.medscimonit.com/fulltxt.php?ICID=883338; M. Gissler et al., *Injury Deaths, Suicides and Homicides Associated with Pregnancy, Finland 1987-2000*, 15 EUR. J. PUB. HEALTH 459 (2005); M. Gissler et al., *Suicides After Pregnancy in Finland, 1987-94: Register Linkage Study*, 33 BRIT. MED. J. 1431 (1996).

[49] Elliot Institute, *Abortions Increase Risk of Maternal Death: New Study*, *available at* http://afterabortion.org/2012/multiple-abortions-increase-risk-of-maternal-death-new-study/ (last visited Jan. 14, 2016) (stating "Women who had two abortions were 114% more likely to die during the period examined, and women had three or more abortions had a 192% increased risk of death").

[50] Roe v. Wade, 410 U.S. 113, 149 (1973).

trimester.[51] Scientific studies now confirm that childbirth is safer than abortion whether in the early or late stages of pregnancy.[52] The incontrovertible evidence based on record linkage studies from Finland, Denmark, and the United States, provides reliable scientific evidence that the risk of death to women is higher than childbirth at *all stages*, including within the first 180 days after a first trimester abortion.[53] Therefore, under *Roe*'s reasoning and the current scientific evidence, the state has a right to enact health and safety regulations in the first trimester.

In addition, the psychological consequences of abortion can lead to physical harm, and therefore, it

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[51] *Id.* (stating "that abortion in early pregnancy, that is, prior to the end of the first trimester, although not without its risk, is now relatively safe").

[52] *See* Saunders & Novick, *Study Confirms Childbirth is Safer for Women than Abortion* (Sept. 13, 2012), *available at* http://www.lifenews.com/2012/09/13/study-confirms-childbirth-is-safer-for-women-than-abortion/ (last visited Jan. 14, 2016). A study in Denmark of almost half a million women complements similar data from Chile and Ireland that confirms legalizing abortion does not decrease maternal mortality rates. *Id.*

[53] Reardon & Coleman, *Short and Long Term Mortality Rates Associated with First Pregnancy Outcome: Population Register Based Study for Denmark 1980-2004*, 18(9) MED. SCI. MONITOR 71-76 (Aug. 2012), *available at* http://www.medscimonit.com/fulltxt.php?ICID=883338. Dr. Reardon asserts that any claims to the contrary are due to reviewers specifically excluding record linkage studies to promote the myth of abortion safety. *See* Reardon, *Rebuttal of Raymond and Grimes*, 79(3) LINACRE Q. 259-60 (Aug. 2012) (criticizing studies that do not use linkage studies).

is important to have continuity of care by the attending physician who understands what transpired during the abortion and the consequences after the abortion. It is well recognized that some women experience sadness, grief, and feelings of loss following an abortion and that it can led to clinically significant psychological disorders such as depression and anxiety.[54] These negative psychological effects of abortion can lead to negative physical consequences such as alcohol and substance abuse.[55] Scientific studies have shown that abortion is "significantly linked to behavioral changes such as promiscuity, smoking, drug abuse, and eating disorders which all contribute to increased risks of health problems."[56] The scientific studies also demonstrate that women who have multiple abortions face a much greater risk of experiencing these complications.[57] Thus, many

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[54] The principle has been recognized by this Court, the Texas Department of Health, and the American Psychiatric Association. *See* Gonzales v. Carhart, 550 U.S. 124, 159 (2007); Tex. Dep't of Health, *A Woman's Right to Know Booklet* at 16, *available at* https://www.dshs.state.tx.us/wrtk/default.shtm (lasted visited Jan. 7, 2016); American Psychiatric Association, *APA Abortion Report* (2008), *available at* http://www.abortionrisks.org/index.php?title=APA_Abortion_Report#Others_Recommending_Screening_and_Doctor.27s_Obligation (last visited Jan. 14, 2016).

[55] Elliot Institute, *Abortion Risks: A List of Major Physical Complications Related to Abortion* (*citing* reliable scientific studies), *available at* http://afterabortion.org/1999/abortion-risks-a-list-of-major-physical-complications-related-to-abortion/ (last visited Jan. 14, 2016).

[56] *Id.*

[57] *Id.*

have advocated that there needs to be appropriate screening.[58]

The scientific studies confirm the real life experiences of post-abortive women. Amicus Cindy Williamson states:

> Afterward [sic] the abortion, my rebellion turned to destructive behavior. I tried to drink away the memory of killing my unborn child, and I turned to drugs. My self-worth plunged, I felt like I didn't deserve to be a mother to the daughter that I had. I lost custody of her because I was unable to keep a job and because of my destructive lifestyle – drinking, drugs, my weight dropping to a dangerous 88 pounds, and not caring about anything.[59]

Amicus Brandi Dudley states:

> I was told over and over this was the best solution to the problem. I was told by people who I respected that having an abortion

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[58] For example, *see* American Psychiatric Association, *APA Abortion Report* (2008), *available at* http://www.abortionrisks.org/index.php?title=APA_Abortion_Report#Others_Recommending_Screening_and_Doctor.27s_Obligation (last visited Jan. 14, 2016) (recommending screening); Gallagher, *Without Pre-Abortion Screening Abortion Endangers Women's Health* (Apr. 27, 2004), *available at* http://www.lifenews.com/2004/04/27/nat-478/ (last visited Jan. 23, 2016) (discussing Dr. Reardon's call for screening based on 63 medical studies).

[59] Statement of Cindy Williamson, *available at* trinitylegal center.org (last visited Jan. 14, 2016).

> would allow me to move on and excel in life. That was a grievously wrong statement because instead of excelling, I began a self-sabotaging lifestyle.[60]

Abortion is a short-term solution with long-term physical and psychological consequences that may begin immediately, but can last for years.[61] The courts have recognized what the post-abortive women have experience. For example, in *Women's Medical Center of Northwest Houston v. Bell*,[62] the Court of Appeals for the Fifth Circuit concluded that "abortion is almost always a negative experience for the patient. "[63] In 2007, this Court recognized that "it seems unexceptionable to conclude some women come to regret their choice to abort the infant life they once created and sustained"[64] and recognized that "Severe depression and loss of esteem can follow."[65]

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[60] Statement of Brandi Dudley, *available at* trinitylegal center.org (last visited Jan. 14, 2016).

[61] *See generally* Schlueter, *40th Anniversary of Roe v. Wade: Reflections Past, Present and Future*, 40 OHIO NO. U. L. REV. 105 (2013) (*citing* women's affidavits); MELINDA TANKARD REIST, GIVING SORROW WORDS: WOMEN'S STORIES OF GRIEF AFTER ABORTION 10 (2000) ("A woman never forgets a pregnancy and the baby that might have been.").

[62] 248 F.3d 411 (5th Cir. 2001).

[63] *Id.* at 418.

[64] Gonzales v. Carhart, 550 U.S. 124, 159 (2007).

[65] *Id.*

B. H.B. 2 Should Be Upheld Because Ambulatory Surgical Centers Benefit and Protect Women and Can Save a Woman's Life When There Are Complications.

ASCs have a "strong track record of quality care and positive patient outcomes"[66] in more than 5,300 ASCs in the United States that perform 23 million surgeries annually.[67] In Texas, there are 430 ASCs providing a high quality, low cost alternative for surgeries.[68] To ensure the quality of care, Texas has enacted common sense safety measures including the requirement for abortions to be done at ASCs.[69] The following is a sample of the ASC standards in five major areas:

- There should be appropriate standards for the "construction and design [of the facilities,] including plumbing, heating, lighting, ventilation, and other design standards. "[70] These are necessary to

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[66] Ambulatory Surgical Center Association, *History of ASCs*, *available at* http://www.ascassociation.org/advancingsurgicalcare/whatisanasc/historyofascs (last visited Jan. 14, 2016).

[67] *Id.*

[68] *See* Texas Ambulatory Surgical Center Society, *Ambulatory Surgery Center Facts*, *available at* http://www.texasascsociety.org/surgery-center-facts (last visited Jan. 14, 2016).

[69] *See generally* Schlueter, *40th Anniversary of Roe v. Wade: Reflections Past, Present and Future*, 40 OHIO NO. U. L. REV. 105 (2013) (urging safety measures such as ASCs to protect women considering an abortion).

[70] TEX. HEALTH & SAFETY CODE ANN. § 243.010(a)(1).

"ensure the health and safety of [surgical] patients."[71]

- "[T]he qualifications of the professional staff and other personnel" should be appropriate for the surgical procedure.[72] Women are entitled to competent medical care for all surgical procedures.
- The facility should have and maintain the necessary "equipment [that is] essential to the health and welfare of patients,"[73] including the necessary emergency equipment if there are abortion complications.
- "[T]he sanitary and hygienic conditions [of] the center and its surroundings" should meet the minimum requirements of other ambulatory surgical centers.[74] Women are entitled to clean facilities and instruments to prevent infection, which may lead to illness or death.
- There must be "a quality assurance program for patient care."[75]

ASCs must comply with an extensive set of inection prevention standards that are monitored

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[71] *Id.*

[72] *Id.* § 243.010(a)(2).

[73] *Id.* § 243.010(a)(3).

[74] *Id.* § 243.010(a)(4).

[75] *Id.* § 243.010(a)(5).

internally at each ASC daily and evaluated by external inspectors trained in the use of a rigorous, detailed infection prevention survey tool.[76] This is important for women due to the risk of infection following an abortion.

ASCs provide for a clean and safe environment to have an abortion. They are an important step in protecting women from abortionists such as Kermit Gosnell whose clinic was called a "house of horrors."[77] The Grand Jury in the Kermit Gosnell case stated:

> The clinic reeked of animal urine, courtesy of the cats that were allowed to roam (and defecate) freely. Furniture and blankets were stained with blood. Instruments were not properly sterilized. Disposable medical supplies were not disposed of; they were reused, over and over again. Medical equipment – such as the defibrillator, the EKG, the pulse oximeter, the blood pressure cuff – was generally broken; even when it worked, it wasn't used. The emergency exit was padlocked shut. And scattered throughout, in cabinets, in the basement, in a freezer, in jars and

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[76] *See* Ambulatory Surgical Center Association, *Quality of Care in ASCs*, *available at* http://www.ascassociation.org/advancingsurgicalcare/qualityandpatientsafety/qualityofcareinascs (last visited Jan. 14, 2016).

[77] The District Attorney described Kermit Gosnell's facility as a "house of horrors." NBC News, *"House of Horrors" Alleged at Abortion Clinic* (Jan. 19, 2011), *available at* http://www.nbcnews.com/id/41154527/ns/us_news-crime_and_courts/t/house-horrors-alleged-abortion-clinic/#.VpVZv73-km0 (last visited Jan. 14, 2016).

> bags and plastic jugs, were fetal remains. It was a baby charnel house.[78]

No woman should have to endure the conditions that existed in the Gosnell "house of horrors." Women deserve better and H.B. 2 provides the safety measures to ensure that this type of conduct does not exist in Texas. ASCs are a means to ensure a clean and safe facility.[79]

It has been reported that the conditions and practices of Kermit Gosnell are not uncommon.[80] For example, Douglas Karpen, a Houston, Texas abortionist, has been described as Gosnell's Texas counterpart.[81] Three employees from his clinic came forward to describe the conditions in those clinics and Karpen's practices.[82] In addition, a lawsuit was filed

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[78] Grand Jury Report, MISC. NO. 0009901-2008 at 2, *available at* http://www.phila.gov/districtattorney/PDFs/GrandJuryWomensMedical.pdf (last visited Jan. 14, 2016). *See generally* Calhoun, *Stopping Philadelphia Abortion Provider Kermit Gosnell and Preventing Others Like Him: An Outcome that Both Pro-choicers and Pro-lifers Should Support*, 57 VILL. L. REV. 1 (2012).

[79] TEX. HEALTH & SAFETY CODE ANN. § 243.010(a)(4).

[80] Jasper, *Another House of Horrors: Gosnell's Abortion Counterpart in Texas* (May 16, 2013), *available at* http://www.thenewamerican.com/usnews/crime/item/15423-another-house-of-horrors-gosnell-s-abortion-counterpart-in-texas (last visited Jan. 14, 2016) (discussing investigations by Life Dynamics and Live Action).

[81] *Id.*

[82] *Id.*

by Melanie Mendoza.[83] According to the complaint, Melanie went to the emergency room because the pain was so intense following the abortion.[84] The Ob-Gyn attending doctor determined that there was a tear in the uterus and Melanie was bleeding internally.[85] The bleeding was so severe and injuries so extensive that the attending doctor elected to do an open procedure.[86] She concluded that the injuries caused by Karpen were "one the worst injuries to the uterus that she had ever seen or read about."[87] Karpen did not have hospital privileges,[88] and therefore, there was no assurance of his qualifications or his ability to provide the continuity of care that Melanie needed.

At an ASC, there is "post-op monitoring" for the required period of time and extended care is given if needed.[89] Both of H.B. 2's provisions requiring ASCs and hospital privileges would have protected Melanie.

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[83] *See* Mendoza v. Karpen et al., Docket number 2014-12321, *available at* http://operationrescue.org/pdfs/Mendoza%20v%20Karpen%20botched%20abortion%20lawsuit.pdf (last visited Jan. 14, 2016).

[84] *Id.* at para. 10.

[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] Enriquez, *"Texas Gosnell" Douglas Karpen No Longer Terminating Unborn Texans* (June 15, 2014), *available at* http://liveactionnews.org/texas-gosnell-douglas-karpen-no-longer-terminating-unborn-texans/ (last visited Jan. 14, 2016).

[89] Affidavit of Dr. Noreen Johnson at Appendix B.

ASCs have monitoring and emergency equipment that can save a woman's life when there are complications. Amicus Eileen Smith knows first hand of the heartbreak when emergency equipment is not available to save a woman's life. Her daughter, Laura Smith, was a twenty-two year-old abortion patient who was thirteen-weeks pregnant when she sought a legal abortion at the Women's Health Center, in Hyannis, MA on September 13, 2007.[90] During the abortion, Laura's heart, pulse, and blood pressure were not monitored, and there was no oxygen source in the room.[91] Abortionist Osathanondh and an office worker who had no training in resuscitation measures were the only ones with Laura during and after the abortion.[92] Osathanondh called Laura's name in an effort to awaken her, but he received no response.[93] He then failed to timely initiate a call to 911. Laura was pronounced dead by the time she arrived at Cape Cod Hospital.[94]

Although Osathanondh tried to deny the allegations, it was later determined that he did not have any means of monitoring Laura's heart, and did not have oxygen or a functioning blood pressure cuff in

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[90] Life Dynamics, *Laura Hope Smith Dead After Legal Abortion*, *available at* https://lifedynamics.com/laura-hope-smith-dead-legal-abortion/ (last visited Jan. 14, 2016).

[91] *Id.*

[92] *Id.*

[93] *Id.*

[94] *Id.*

the room during Laura's abortion.[95] A report issued by the Board of Registration in Medicine said the abortion doctor, *"engaged in conduct that calls into question his competence to practice medicine."*[96] The board also concluded that he *"failed to adhere to basic cardiac life support protocol"* and did not call 911 in a timely manner.[97]

If health and safety measures had been in place in Massachusetts when Laura Smith had her abortion, this tragedy could have been avoided. Examples such as Laura's case are exactly why H.B. 2 is necessary and important to save the lives of Texas women. Amici urge this Court to uphold the common sense protections of H.B. 2.

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[95] Bennington Banner, *Trial Set for Mass. Doc in Abortion Patient Death* (Sept. 13, 2010), *available at* http://www.benningtonbanner.com/news/ci_16067872 (last visited Jan. 14, 2016).

[96] *See* Life Dynamics, *Laura Hope Smith Dead After Legal Abortion*, *available at* https://lifedynamics.com/laura-hope-smith-dead-legal-abortion/ (last visited Jan. 14, 2016).

[97] *Id.* As a result of Laura's death, prosecutors charged Osathanondh with manslaughter. In 2010, he was sentenced to six months in prison, but served only three months. Subsequently Eileen Smith filed a civil suit which was settled and Osathanondh agreed to pay the family a substantial sum of money as a punitive measure. *Id.*

C. The Requirement That Doctors Have Privileges at Local Hospitals Is Implicitly Good for Women and Provides Continuity of Their Care When Complications Arise.

At least fifteen states have adopted laws or regulations that require abortionists to have admitting privileges at a nearby hospital.[98] Generally, when a doctor has admitting privileges, the doctor can transfer a patient to a local hospital if complications arise during or after an abortion and can provide the continuity of care that is needed.[99]

H.B. 2 requires that abortionists have admitting privileges at local hospitals within thirty miles from the place of the abortion.[100] The Texas Legislature stated that the purpose of this requirement was to raise the standard and quality of care for women

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[98] *See* ALA. CODE § 26-23E-4; ARIZ. REV. STAT. § 36-449.03; ARK. CODE ANN. § 20-16-1504; FLA. STAT. § 390.012; IND. CODE § 16-34-2-4.5; KAN. STAT. ANN. § 65-4a09; LA. STAT. ANN. § 40:1299.35.2; MISS. CODE ANN. § 41-75-1; MO. REV. STAT. § 188.080; N.D. CENT. CODE § 14-02.1-04; OKLA. STAT. tit. 63, § 1-748; TENN. CODE ANN. § 39-15-202; TEX. HEALTH & SAFETY CODE ANN. § 171.0031; UTAH ADMIN. CODE R. 432-600-13; WIS. STAT. § 253.095.

[99] Shimabukuro, *Abortion, Hospital Admitting Privileges, and Whole Woman's Health v. Cole* (Sept. 25, 2015), *available at* https://www.fas.org/sgp/crs/misc/R44205.pdf (last visited Jan. 14, 2016) (providing a report for the Congressional Research Service).

[100] TEX. HEALTH & SAFETY CODE ANN. § 171.0031(a)(1).

seeking abortions, and protects their health and welfare.[101]

A physician having local hospital privileges is important for several reasons. First, hospital privileges help ensure qualified and competent doctors work at the hospital. This is because:

> The physicians on the hospital's credentialing committee investigate the applicant's background to determine the extent of his past medical training and performance, whether he is licensed and board certified, he carries malpractice insurance, and any other information that they believe is relevant.[102]

Second, physical complications can occur during or after an abortion that requires hospitalization.[103] Some reports claim that approximately 1,000 Texas women per year require hospitalization due to complications of the abortion.[104] Planned Parenthood's expert admitted at the trial concerning H.B. 2 that

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[101] *See* Whole Woman's Health v. Cole, 790 F.3d 563, 576 (5th Cir. 2015).

[102] Neff, *Physician Staff Privilege Cases: Antitrust Liability and the Health Care Quality Improvement Act*, 29 WM. & MARY L. REV. 609, 613-14 (1988).

[103] Affidavit of Carol Everett at Appendix A.

[104] Sullenger, *Nearly 1,000 Texas Women Hospitalized Every Year After Botched Abortions* (Apr. 22, 2014), *available at* http://www.lifenews.com/2014/04/22/nearly-1000-texas-women-hospitalized-every-year-after-botched-abortions/ (last visited Jan. 14, 2016).

210 women went to the emergency room.[105] The Court of Appeals stated that:

> During these proceedings, Planned Parenthood conceded that at least 210 women in Texas annually must be hospitalized after seeking an abortion. Witnesses for both sides further testified that some of the women who are hospitalized after an abortion have complications that require an Ob/Gyn specialist's treatment.[106]

Third, in many hospitals, specialists such as Ob-Gyns are not on call.[107] Relying on the comprehensive testimony and data by Dr. John Thorp, the Court of Appeals for the Fifth Circuit recognized the "lack of adequate on-call coverage by specialist physicians, including Ob/Gyns."[108] Thus, the court concluded that "requiring abortion providers to obtain admitting privileges will reduce the delay in treatment and decrease health risk for abortion patients with critical complications."[109] Such safety measures are reasonable and protect women.

Fourth, an abortionist without having local hospital privileges is like an itinerant surgeon which is

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[105] Planned Parenthood v. Abbott, 748 F.3d 583, 595 (5th Cir. 2014).

[106] *Id.*

[107] *Id.* at 592.

[108] *Id.*

[109] *Id.*

proscribed.[110] In states such as South Dakota, the abortionist is flown in from another state for the day to do abortions and flies home at the end of the day.[111] Therefore, if a woman has complications, "local doctors who are strangers to the patient and were in no way involved in the abortion procedure must see her."[112] This practice is not in the best interests of women.

In fact, the American College of Surgeons has standards concerning the relationship of the surgeon to the patient and its proscription of what is called "itinerant surgery."[113] Part of the ethical responsibility of the surgeon is to "ensure appropriate continuity of care of the surgical patient."[114]

In Texas, if the abortionist does not have local hospital privileges, he or she would not be able to

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[110] *See* American College of Surgeons, *Statement of Principles*, subsection F, *available at* https://www.facs.org/about-acs/statements/stonprin#anchor172291 (last visited Jan. 14, 2016).

[111] S.D. Task Force Report, *available at* http://www.dakotavoice.com/Docs/South%20Dakota%20Abortion%20Task%20Force%20Report.pdf 18 (last visited Jan. 14, 2016).

[112] *Id.*

[113] *Id.* "Itinerant surgery involves the practice of a physician outside the physician's normal geographical area of practice to perform surgery where the physician is not personally involved in the original diagnosis or preparation of the patient and is not involved in follow-up care." *Id.* at n.5.

[114] *See* American College of Surgeons, *Statement of Principles*, subsection F, *available at* https://www.facs.org/about-acs/statements/stonprin#anchor172291 (last visited Jan. 14, 2016).

provide the continuity of care that is critically necessary when complications occur. This in essence is a de facto itinerant surgeon.[115]

In addition, it is important for a woman to have an ongoing relationship with her doctor as this Court surmised in *Roe* because complications can arise either immediately or over time. The scientific studies demonstrate that approximately ten percent of post-abortive women suffer from immediate complications.[116] Of this number, one-fifth or two percent were considered major complications.[117] Some complications take time to develop and will not be apparent for days, months or even years.[118]

The scientific studies confirm the real life experiences of post-abortive women. Amicus Joyce Zounis states that:

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[115] Affidavit of Carol Everett at Appendix A (stating that some of her abortionists lived some distance from their clinics and would move from clinic to clinic).

[116] Elliot Institute, *Abortion Risks: A List of Major Physical Complications Related to Abortion* (*citing* studies), *available at* http://afterabortion.org/1999/abortion-risks-a-list-of-major-physical-complications-related-to-abortion/ (last visited Jan. 14, 2016).

[117] *Id.*

[118] *Id. See generally* JOHN C. WILKE & BARBARA H. WILKE, ABORTION: QUESTIONS AND ANSWERS 50 (2003) ("5 years is common, 10 or 20 not unusual."); Elliot Institute, *Abortion Complications*, *available at* http://afterabortion.org/1990/abortion-complications/ (last visited Jan. 14, 2016) ("The best available data indicates that on average there is a five to ten year period of denial during which a woman who was traumatized by her abortion will repress her feelings.").

> Eleven years, three clinics, two states, seven abortions, and not once was I told of the physical risks I would suffer later: the necessity of bi-lateral mammograms and fear of breast cancer; ovarian cysts; being bed ridden for five months in my last pregnancy and having to explain the possibly [sic] of "mommy dying" to my four young children due to placenta previa, which resulted in my losing all but two pints of blood; and, a partial hysterectomy at delivery.[119]

Amicus Toni Cordell understands the physical consequences of abortion. She states that although the baby was gone, the consequences for her body began less than a year later.[120] Her uterus collapsed and required a partial hysterectomy. There were eventually seven surgeries which removed all of her female organs and had to rebuild her bladder and urethra.

The physical complications may have life-long consequences. Jackie Bullard states that:

> Five days later, I went to the hospital with cramping, bleeding, and running a fever. I had a raging infection, and an emergency D & C was done to scrape out the baby parts that had been left inside of me. After

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[119] Statement of Joyce Zounis, *available at* trinitylegal center.org (last visited Jan. 14, 2016).

[120] Statement of Toni Cordell is on file with Trinity Legal Center.

> unsuccessful fertility treatments, a test revealed scar tissue damage from the complications of my incomplete abortion. When the doctor told me I could never have children, I was devastated. That day I knew I had taken the life of the only child I would ever carry.[121]

Therefore, when complications arise, it is not in the best interests of the woman to have local doctors who are "strangers" to the patient and were not involved in the abortion procedure. Itinerant surgery is proscribed. Thus, for the health and safety of women, H.B. 2 provides a reasonable requirement that an abortionist have local hospital privileges.

D. Having Hospital Privileges Supports *Roe*'s Assumption of a Normal Doctor-Patient Relationship.

A doctor having hospital privileges would support this Court's assumption in *Roe* of a normal doctor-patient relationship by providing for a woman's continuity of care after the abortion. Women considering an abortion should be given the same continuity of care that any surgical patient currently has and would expect as a normal doctor-patient relationship.

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[121] Statement of Joyce Zounis, *available at* trinitylegal center.org (last visited Jan. 14, 2016).

In the abortion industry, normal doctor-patient relationships are not formed.[122] Generally, patients do not have continuity of care from the abortion provider, but patients are "told if they had a problem to go to the nearest Emergency Room."[123] This is neither continuity of care nor a normal doctor-patient relationship.

At the heart of *Roe* is the assumption that the abortion decision should be made by a woman in consultation with her personal doctor.[124] In its decision, the Court repeatedly referenced the assumption that the woman's decision would be made privately in consultation with her physician. Abortion practice, however, does not usually involve a normal doctor-patient relationship, nor is it a voluntary, informed private decision between a woman and her doctor.[125] Usually women do not see the abortionists until just before the procedure is performed.[126]

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[122] Affidavit of Dr. Noreen Johnson at Appendix B. Dr. Johnson performed abortions for approximately five years and is well acquainted with the abortion industry. *Id.*

[123] *Id.*

[124] *See* Roe v. Wade, 410 U.S. 113, 153 (1973) ("All these are factors the woman and her responsible physician necessarily will consider in consultation.").

[125] *See* S.D. Task Force Report, *available at* http://www.dakotavoice.com/Docs/South%20Dakota%20Abortion%20Task%20Force%20Report.pdf 16-17 (last visited Jan. 14, 2016) (finding "no true physician-patient relationship").

[126] *Id.* at 16 (finding the abortionist "sees the pregnant mother for the first time in the procedure room, only after the

(Continued on following page)

While the Court's opinion in *Roe* focused on the woman's initial decision to obtain an abortion, the underlying assumption that the attending physician would be involved – by parity of reasoning – the woman should have the benefit of counsel from her physician if complications should arise post-abortion.

For example, the physician who performed the abortion would normally be in the best position to assess the complication, based on his or her knowledge of the woman's condition and the procedures that either had been used, or not used, during the abortion. It would be potentially harmful to the woman to be admitted to a hospital post-abortion, and not have the advice and care of the physician who performed the abortion – a medical procedure which the Court itself acknowledges can lead to complications.[127]

Documents are available on a clearinghouse website concerning abortionists' conduct where there should have been an ongoing doctor-patient relationship which would have helped and benefited the woman.[128] For example, abortionist James Pendergraft, a Florida abortionist, sent a patient to the

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consent form has been signed and the woman has made her commitment to undergo the abortion").

[127] Roe v. Wade, 410 U.S. 113, 145-46 (1973).

[128] The website Abortion.Docs.org is a clearinghouse for information from across the nation. The searchable database has documents such as health code violations, abortion injuries, malpractice claims, disciplinary action, and criminal conduct.

hospital for a potential uterine perforation, but he failed to tell the physicians at the hospital that he had already removed the baby's leg.[129] Because the hospital physician did not know this, he had to search the woman's uterus and then do X-rays and a CT scan to make sure he did not cause an infection by leaving the missing body part in her uterus. The Administrative Law Judge found that Pendergraft "breached the standard of care" which constituted medical malpractice.[130] This case illustrates the problem of not having the continuity of care from the attending physician.

H.B. 2 supports the belief that a woman should have the medical advice of her physician post-abortion. This is certainly consistent with *Roe*'s assumption that there would be an ongoing normal doctor-patient relationship. If that physician does not have admitting privileges where his patient must seek medical attention, then the information may be incomplete or limited to remote transmission of information as demonstrated in the Pendergraft case. This is a serious problem because "80 percent of serious medical errors involve miscommunication beween caregivers when patients are transferred or

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[129] Dep't of Health, Board of Medicine v. Pendergraft, State of Florida Division of Administrative Hearings, DOH case No. 10-0208 (2010), *available at* http://abortiondocs.org/wp-content/uploads/2012/01/pendfinal012610.pdf (last visited Jan. 14, 2016).

[130] *Id.* at 20-21. Based on the findings, the Administrative Law Judge imposed a two-year suspension, followed by a three-year probation, and a fine of $20,000.00. *Id.* at 25.

handed-off."[131] Women should have the benefit of her attending physician's continuity of care so that any comlications can be accurately and efficiently addressed.

There are "serious and detrimental effects for women" if H.B. 2 is not upheld.[132] This is because it would "(1) keep the abortion doctor unaccountable to his patient and to the community in which he practices; (2) allow him to provide women with substandard medical care which places their lives in danger; and, (3) would protect the doctor and harm the woman."[133]

Therefore, H.B. 2's requirement for abortionists to have hospital privileges is necessary for the health and safety of women and supports this Court's assumption in *Roe* of a normal doctor-patient relationship.

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[131] Planned Parenthood v. Abbott, 748 F.3d 583, 592 (5th Cir. 2014) (*citing* testimony of Dr. John Thorp referring to several significant studies).

[132] Affidavit of Dr. Noreen Johnson at Appendix B.

[133] *Id.*

III. THIS COURT HAS RECOGNIZED THAT BROAD DEFERENCE SHOULD BE GIVEN TO LEGISLATIVE FINDINGS AND ENACTMENTS, AND THEREFORE, THE COURT OF APPEALS' DECISION SHOULD BE AFFIRMED.

A. Health Issues Are Complex Issues That Are Fact Bound and Involve National and State Policy That Are Best Left to the Legislative Branches of Government.

For over a century prior to *Roe v. Wade*[134] and *Doe v. Bolton*,[135] health issues such as abortion were traditionally state issues.[136] This Court recognized that under what was later called the state's "police power," the states could regulate "health laws of every description."[137] Furthermore, this Court has given deference to legislative judgments.[138]

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[134] 410 U.S. 113 (1973).

[135] 410 U.S. 179 (1973).

[136] Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 204 (1824).

[137] *Id.* at 203.

[138] Gonzales v. Carhart, 550 U.S. 124, 163 (2007) (stating state and federal legislatures have wide discretion to pass legislation where there is medical and scientific uncertainty); Turner Broadcasting System, Inc. v. F.C.C., 520 U.S. 180, 195 (1997) (stating substantial deference should be given because legislature is better equipped to amass and evaluate the vast amounts of data on legislative issues and out of respect for legislative authority); Dominion Hotel v. State of Arizona, 249 U.S. 265, 268 (1919) (stating deference due to legislative judgments has been repeatedly emphasized).

Since *Roe*, this Court has continued to recognize that states may make reasonable regulations that do not impose an undue burden for the health and safety of women.[139] In *Planned Parenthood v. Casey*, this Court recognized that because the State has a substantial interest in the life of the unborn child, the State may promulgate regulations that do not create an undue burden on the woman's right to decide.[140] In particular, regulations that are "designed to foster the health of a woman seeking an abortion are valid if they do not constitute an undue burden."[141] This Court recognized that "[a]s with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion."[142]

Furthermore, this Court has upheld health regulations that "are not efforts to sway or direct a woman's choice, but rather are efforts to enhance the deliberative quality of that decision or are neutral regulations on the health aspects of her decision."[143] The Texas Legislature did not attempt to sway a woman's decision but to protect her health once the decision is made.

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[139] *See* Gonzales v. Carhart, 550 U.S. 124, 146 (2007); Planned Parenthood v. Casey, 505 U.S. 833, 876 (1992).

[140] Planned Parenthood v. Casey, 505 U.S. 833, 876 (1992).

[141] *Id.* at 877.

[142] *Id.* at 878.

[143] *Id.* at 917 (Stevens, J., concurring in part and dissenting in part) (providing examples of valid regulations).

As long as there is a "commonly used and generally accepted method" of abortion, there is not a "substantial obstacle to the abortion right."[144] Specifically, this Court stated in *Gonzales*[145] that "[c]onsiderations of marginal safety, including balance of risks, are within the legislative competence when the regulation is rational and in pursuit of legitimate ends."[146] H.B. 2's effort to protect the health and safety of women is a legitimate end as articulated by this Court.

As one federal court recognized: "Historically, laws regulating abortion have sought to further the state's interest in protecting the health and welfare of pregnant women."[147] In furtherance of its interest, the State of Texas passed H.B. 2 to protect pregnant women from the significant known risks and complications that can occur during and after an abortion. This is within the State's authority and competence, and therefore, should be given deference.

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[144] Gonzales v. Carhart, 550 U.S. 124, 165 (2007).

[145] 550 U.S. 124 (2007).

[146] *Id.* at 166.

[147] McCormack v. Hiedeman, 694 F.3d 1004, 1010 (9th Cir. 2012).

B. The H.B. 2 Provisions Are Within This Court's Constitutional Framework and Should Be Upheld.

Since *Casey*, the Texas Legislature has properly exercised its authority to protect women who are considering an abortion. For example, the Texas Legislature passed the State's Woman's Right to Know law[148] and the Texas Department of Health Services produced *A Woman's Right to Know Booklet*.[149] The Booklet was produced after extensive hearings by the medical board to provide accurate, scientifically based information for women considering an abortion. In addition, there is an annual review of the Booklet to ensure that information is "based on current and relevant science and evidence-based literature, medical professional resources, and government health and medical resources."[150]

The Texas Legislature's enactment of H.B. 2 is another step in protecting women by providing

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[148] During the 2003 session, the Texas Legislature passed the Woman's Right to Know Act (House Bill 15), codified at TEX. HEALTH & SAFETY CODE § 171.001 *et seq*.

[149] Texas is just one of twenty-seven states that have *A Woman's Right to Know* law and booklets so that a woman will know the medical risks associated with abortion and have scientifically accurate medical facts about the development of her unborn child. *See A Woman's Right to Know: Casey-style Informed Consent Laws*, *available at* http://www.nrlc.org/uploads/stateleg/WRTKFactSheet.pdf (last visited Jan. 14, 2016).

[150] *A Woman's Right to Know*, *available at* https://www.dshs.state.tx.us/wrtk/default.shtm (last visited Jan. 14, 2016).

common sense safety laws for women considering an abortion just as any other surgical out-patient has.[151] As the Texas law states, the "rules must contain minimum standards to protect the health and safety of a patient of an abortion facility. "[152]

When then-Governor Perry signed H.B. 2, he stated: "It is our responsibility and duty to improve the quality of care women receive, ensuring that any procedure they undergo is performed in clean, sanitary and safe conditions, by capable personnel."[153]

Reflecting back on the passage of H.B. 2, then-Lt. Governor Dewhurst emphasized the importance of the law for the protection of women.[154] He stated: " it is useful to remember that the bill made Texas the 28th state to order the highest standards of care

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[151] In Texas, there are 430 ambulatory surgery centers. *See* Texas Ambulatory Surgical Center Society, *Ambulatory Surgery Center Facts*, *available at* http://www.texasascsociety.org/surgery-center-facts (last visited Jan. 14, 2016). Today, almost 75% of all surgeries are performed on an outpatient basis and more than half of them are done in an ambulatory surgery center. *Id.*

[152] TEX. HEALTH & SAFETY CODE § 245.010(a).

[153] Smith, *Perry Signs HB 2*, The Austin Chronicle (July 18, 2013), *available at* http://www.austinchronicle.com/daily/news/2013-07-18/perry-signs-hb2/ (last visited Jan. 14, 2016).

[154] Dewhurst, *One Year Later: HB 2 and the Pro-Life Movement in Texas* (Jul. 18, 2014), *available at* http://townhall.com/columnists/daviddewhurst/2014/07/18/one-year-later-hb-2-and-the-prolife-movement-in-texas-n1863568/page/full (last visited Jan. 27, 2016).

at abortion facilities." In addition, the Legislature "appropriated $179 million in new state funding for women's health services including preventative care and screenings. The 83rd Legislature should be remembered for the advances we made in women's health."[155]

The Texas Legislature is not alone in providing safety laws. For example, twenty-two states require ASC-type facilities[156] and ten states require abortionists to have hospital privileges.[157] Another nine states require that there be either hospital privileges or an alternative agreement.[158] Thus, Texas has taken reasonable and common sense steps to protect women based on reliable scientific data and what is required for other types of out-patient surgeries. H.B. 2 is reasonable and should be upheld.

Furthermore, legislative bodies, unlike courts, are able to hold hearings, review the scientific data, and enact or revise health and safety laws to keep pace with the scientific evidence.[159] If legislatures are

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[155] *Id.*

[156] Guttmacher Institute, *State Policies in Brief* (Dec. 1, 2015), *available at* http://www.guttmacher.org/statecenter/spibs/spib_TRAP.pdf (last visited Jan. 14, 2016).

[157] *Id.* (stating that in five states the law is temporarily enjoined pending a final decision in the courts).

[158] *Id.* (stating Arkansas' policy takes effect later in 2016).

[159] *See* McCorvey v. Hill, 385 F.3d 846, 852 (5th Cir. 2004) (Jones, J., concurring but also writing the majority opinion for the panel). Judge Jones stated that she could not "conceive of

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not able to evaluate the evolving medical knowledge and scientific evidence, then it "leaves our nation in a position of willful blindness."[160] Thus, this Court has correctly given deference to legislative enactments and findings.

The Amici urge the Court to give deference to H.B. 2 which was enacted to protect the health and safety of women seeking an abortion once they have made the decision to have an abortion. H.B. 2's safety provisions are based on current, scientific evidence and thus should be upheld.

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any judicial forum in which McCorvey's evidence could be aired." *Id.* By constitutionalizing the issue, legislative bodies cannot meaningfully debate the scientific evidence and this has led to a "perverse result" which affects over a million women each year. *Id.*

[160] *Id.* at 853.

CONCLUSION

For the foregoing reasons, the requirements of H.B. 2 should be upheld and the decision of the United States Court of Appeals for the Fifth Circuit affirmed.

Respectfully submitted,

LINDA BOSTON SCHLUETER

Counsel for Amici Curiae

APPENDIX A

Affidavit of Carol Everett

STATE OF TEXAS	§	KNOW ALL
	§	MEN BY THESE
COUNTY OF WILLIAMSON	§	PRESENTS

BEFORE ME, the undersigned authority on this day personally appeared Carol Everett who is personally known to me, and after being by me first duly sworn according to law on her oath did depose and say that:

1. "My name is CAROL EVERETT. I am over the age of eighteen (18) years of age and I am fully competent to make this Affidavit. I reside in Round Rock, Texas. I have personal knowledge of the facts stated herein and the following is true and correct.

2. I know firsthand about abortion and the abortion industry. I have been both a consumer and provider. I was involved in the operation of abortion facilities from 1977 to 1983, overseeing 35,000 abortions. I was formerly part owner of Dallas' largest abortion chain.

3. Since leaving the abortion industry, I have been committed to safeguarding the health of women and their babies all over this nation. I speak to the men and women who have experienced an abortion to offer a message of healing and hope.

4. I formed The Heidi Group to help girls and women in unplanned pregnancies make positive, life-affirming choices for themselves and their babies. Our role is to connect girls and women to the best resources available. At the Heidi Group, we affirm the dignity and value of girls, women, and families. It is our goal to make sure that before a girl or a woman walks through the door of an abortion facility, she sees the full picture of the resource community waiting to embrace her and her unborn baby.

My Abortion Experience

5. I was married, had an 8 year-old daughter and a 10 year-old son when I found myself pregnant again. When I excitedly told my husband of the pregnancy, his initial reaction was, "you'll just have to have an abortion."

6. Searching for help, I went to my doctor and told him that my husband didn't want me to have this baby. Without discussion, he offered an illegal abortion. I was looking for someone to tell me not to have the abortion, but I ran into an abortion salesman. And that is what happens in our nation today as employees of abortion facilities may earn a higher rate per hour or a commission for abortion appointments completed. Every physician performs abortions on a straight commission. Abortion physicians are only paid for their services after the abortion procedure is complete. Abortion physicians strive

to perform ten to twelve first trimester abortions per hour, paid approximately one-third of the total fee. Second and third trimester abortions require more of the physician's time because the baby's muscle structure is more strongly developed and takes longer to remove. Second and third trimester physician procedure fees are approximately fifty percent of the total cost. A late term physician specialist strives to perform two to three second and third trimester abortions per hour.

7. When I woke from my abortion, I picked up the telephone, and literally started working from my hospital bed, not realizing that I was already running from that decision. I know first-hand the devastation of abortion – – my life rapidly went downhill. Within a month, I was having an affair which I had never done before. Very soon I started drinking; I had not ever drunk in my life. Shortly thereafter, my marriage broke up.

8. Then I started seeing a psychiatrist daily. At the rate of $125.00 an hour, I could not go on with this very long. So I decided to do what I called, "get hold of myself." I changed everything I could in my life, except my children. I got away from the job I'd had; now away from my husband, and decided I would make it on my own. What I'm telling you is the story about how my life went along at a pretty good level for a while, and the moment I had that abortion, it went straight downhill. I

think that is what happens to every woman who has an abortion.

9. Abortion is devastating to women and babies, but it also has very negative consequences for fathers. My former husband now struggles with our abortion.

The Abortion Business

10. When I did "get hold of myself", I went to work for a man who had a medical supply business. At about this time, abortion became legal in the State of Texas, and very soon we had a new account that was very profitable. The medical supply company was making thousands of dollars a month from this one account. My employer determined to understand exactly what sort of business this new account was and found it to be an abortion facility. This man who told me he never wanted to see an abortion, never wanted to know what an abortion really was, opened his first abortion clinic, and soon he had four.

11. All this time he kept inviting me to join him. He said that with my daily contact with physicians, I was in a perfect position to sell abortions for his clinics. He would pay $25 per completed abortion. I kept selling medical supplies and sold a few abortions along the way. But the day came when I needed to make more money. So I told him that I was quitting my job; I wanted to go with another company. So, he got me on the fringe of the

abortion industry by asking me to set up referral clinics all over Texas, Oklahoma and Louisiana. And I did that for a while and it was quite profitable.

12. Then he asked me to work at one of the clinics for a month. I immediately recognized ways to sell more abortions. With just a very few small changes, in one of his clinics, abortions went from 190 to 195 per month to over 400 per month. Our telephone counselors booked abortions for both the Dallas and Fort Worth clinics. The last month I was with him in those two clinics, he was doing something over 800 abortions a month. I personally participated in approximately 10% of the abortion procedures performed at the two facilities.

13. In addition to other duties, I was in charge of training employees we called "counselors." These counselors were not trained to counsel a woman about her options or to provide accurate, truthful information about an abortion. Information about fetal development or the risks of abortion was not provided. We did not counsel our patients as to the potential physical and emotional consequences of having an abortion. What we did could not be considered counseling. Our people were trained as telemarketers. We learned how to exploit the fears of our callers. We sold abortions. I believe that states should require full and accurate informed consent counseling and should require statistical reporting to

compile data for accurate informed consent forms.

14. The strategy of the abortion industry is to gain the trust of young people by offering secrecy and promiscuity via free and inexpensive birth control, and then banking on their inevitable return when pregnancy occurs. We deliberately prescribed low-dosage birth control to help ensure that pregnancies occurred. The goal was three to five abortions from girls between the ages of 13 and 18. The record was nine from one girl.

15. It has been my experience that when a woman or a young girl learns that she is pregnant, she may not want an abortion. She may only want information. The person who answers the phone in an abortion facility is paid and trained to be her friend. Her job is to sell her an abortion by asking questions and leading her to believe an abortion is her only option – the answer to every question.

16. Since I had doubled his business, I asked for an equity interest in the business. He said no. I placed my Yellow Page ad to come out in six months for my own abortion clinic. We opened the first clinic. And then I opened a second clinic in the Dallas area. We did over 500 abortions a month in those two clinics. I was compensated at the rate of $25.00 per case, plus one-third of the clinics, so you can imagine what my motivation was. I sold abortions. I had made $150,000; was on target in 1983 to make about $260,000; and my

goal when we opened our five clinics was to complete 40,000 abortions annually. I would have been making a million dollars a year.

17. Abortion is a very lucrative business. Abortion facilities sell abortions. They don't sell keeping the baby. They don't sell placing the baby for adoption. The only "choice" offered by the abortion industry is abortion.

18. It is becoming more lucrative with the RU-486 regimen. These medical abortions sell pills with minimal oversight and follow-up. The potential of an RU-486 abortion is that if the pill does not completely abort the baby, the woman may be subjected to a second procedure – a surgical abortion in some cases for a second full fee.

19. Since 2000 when the FDA approved the RU-486 regimen, I have met with women who have taken RU-486. They have had more severe physical and psychological complications than women who have had surgical abortions. For example, the physical issues include severe hemorrhaging and pain from RU 486. In addition, some of the most severe post-abortion syndrome occurs because the women actually see the baby after it is expelled.

20. Abortion facilities do not discuss the baby in accurate terms. Even when the women [sic] asks if it is a baby, abortion clinic employees answer "no, it's a product of conception"; "it's a blood clot"; "it's a piece of tissue" They do not tell them it's a fetus because that almost

humanizes it too much. It is never a baby. We never explained that every baby had to be reconstructed in the Central Supply room to be certain all parts had been removed. If a body part is not present, the woman may have to return to the procedure room to complete removal of the baby body parts and thus prevent infection.

21. This is what causes such psychological trauma certainly with RU-486 because the woman sees for herself that she was lied to and it really is a baby that she has just expelled in the toilet or shower.

22. They also mislead women as to what will occur. For example, women ask if it will hurt. They say no and explain that the uterus is a muscle and it is a cramp to open it; a cramp to close it; it is a slight cramping sensation. Because every woman has had cramps, they think that is what they have experienced before. But women who have taken RU-486 state that it is severe cramping like they have never experienced before.

23. I have worked with a Houston woman who was given RU-486. Ten weeks later, she thought she was pregnant again, but when she went to the abortion facility she learned she had an incomplete abortion. This time, for a second fee, a surgical abortion was performed and she was sent home with an IV in her arm. When she called the abortion facility, she was told to meet clinic staff in a park and they would take it out. Recognizing this

was substandard medical care, the woman went to an Emergency Room where a physician removed the IV.

24. Many women who had abortions at my clinics had major physical complications requiring hospitalization. The last 18 months I was in the abortion business, one out of every 500 women had major surgery requiring hospitalization. (Hysterectomy, colostomies due to bowel perforation and one woman bled to death. We moved that woman from the clinic so the staff would not be aware of the death.) Patients were moved to hospitals by private car – never by ambulance. (An ambulance at an abortion facility was considered negative advertisement.) We transported patients in crisis in some cases more than 30 miles, but at the very least across town to a hospital we trusted to keep the abortion complication admission secret. Our medical director always had a hospital that he promised his private admissions in return for handling the next abortion clinic emergency. If the specialties of other physicians were required, the medical director called in favors from friendly physicians. The patient and her needs were secondary to the protection of the clinic and its reputation even to the point of falsification of the medical record. The requirement of admitting privileges for abortion physicians would have forced our abortion physicians to consider the needs of the woman in crisis before the reputation of the abortion clinic.

25. Based on my experience, I now believe that women should have been given accurate information about the physical and emotional consequences of abortion so that they could make an informed decision.

26. Some of our abortion physicians were circuit rider physicians, living some distance from our clinics. They moved from abortion clinic to abortion clinic, working for different owners.

27. Ordinary day surgery and physician's offices meet the standards of Medicare in order to be paid for services by insurance. Abortion is a cash or credit card business, thus no need to meet the minimum standards of quality health care.

28. Based on the fact that abortion physicians strive to perform a minimum of 10 to 12 abortions per hour, it is almost impossible to keep surgical instruments clean and sterile. For instance, 50 abortions are scheduled for a day. Two abortion physicians are working at a rate of 20 to 24 abortions an hour. The abortion facility only has 21 sets of surgical instruments. The physicians are each working from two rooms. The first two procedures are completed and both physicians rush to the next room to perform the second surgical procedure. The instruments and the "products of conception" are sent to Central Supply. The technician reconstructs the babies to be certain all body parts are removed. (If a baby's body part is missing, the woman may

be subjected to a second abortion procedure.) The instruments are washed, placed in sterile wrap and placed in a steam sterilizer. The temperature for sterility is required to reach 270 degrees. It takes several minutes for the temperature to be reached. After holding the temperature at 270 degrees for 20 minutes to sterilize instruments, it takes some time for the steam to release. The instruments are removed but they are far too hot to touch. By now the technician has a stack of instruments ready to go but the problem now is that the two abortion physicians are so far ahead of the sterilization process, it is humanly impossible to keep the instruments sterile. The unwritten protocol of the abortion clinic at this point changes from complete sterilization to using a product like Cidex that is supposed to sterilize but again, the problem of time. Now the tech must wash instruments and leave in the sterilization product long enough to completely sterilize. At some point, the process is abandoned and the technician simply must supply the abortion physician with instruments to continue his work at 10 to 12 abortions each hour. Instruments are washed and returned to the line for procedures. I saw one abortion physician use instruments straight out of the sterilizer that were so hot, he had to use an oven mitt to insert the dilators. That woman's cervix was surely burned, even scarred. What sort of complications with future fertility? In one of the 450 existing ambulatory surgical facilities in Texas, the medical

industry standard requirement for surgical sterilization of all instruments would protect the health of women. The simple requirement for the physician to write surgical notes before the next procedure would be a second safety factor for the women and at the very least would insure accurate medical records for each patient.

29. I support the health and safety provisions of HB 2 because ASCs have strict requirements for cleanliness and sterilization which would correct the problems in abortion clinics. In addition, having hospital admitting privileges provides continuity of care when complications occur for either surgical or medical abortions.

Further Affiant sayeth not."

/s/ Carol Everett
Carol Everett

SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned authority, on this 18 day of January 2016.

[SEAL]	KAMALI KAYE BARRON Notary Public, State of Texas My Commission Expires August 20, 2019	/s/ KBarron NOTARY PUBLIC IN AND FOR THE STATE OF TEXAS Notary Public, County, Texas My Commission Expires: 8/20/19

APPENDIX B

Affidavit of Dr. Noreen Johnson

STATE OF TEXAS	§	KNOW ALL
	§	MEN BY THESE
COUNTY OF BRAZOS	§	PRESENTS

BEFORE ME, the undersigned authority on this day personally appeared Noreen Johnson who is personally known to me, and after being by me first duly sworn according to law on her oath did dispose [sic] and say that:

1. "My name is Noreen Johnson. I am over the age of eighteen (18) years of age and I am fully competent to make this affidavit. I currently reside and practice Gynecology in Bryan/College Station Texas. I am Board Certified in Obstetrics and Gynecology since 1981 and a Fellow of the American College of OB-GYN since 1983. I feel fully qualified to make this affidavit based on my clinical knowledge and personal experience as an ex abortion provider. The facts stated herein are accurate and true.

2. I was trained in the abortion procedure during my Residency at MLK Hospital in Los Angeles, California. I moonlighted in three (3) different abortion clinics during the years of 1979-1981, performing on a busy Saturday up to thirty (30) abortions a day and during a weekday up to 10 abortions. Pregnancies less than ten (10) weeks took no more than six (6) minutes each and ten to fourteen (10-14)

weeks up to ten (10) minutes. Patients were told if they had a problem to go to the nearest Emergency Room.

3. As we consider H.B. 2 one must recognize that the abortion clinic is unlike other medical offices where less invasive procedures are performed and more regulations are imposed. Doctors seeing patients in a community clinic adhere to a standard of care which requires them to have hospital privileges where they practice medicine and be available to their patients for follow up in the event of problems or complications. Failure to do so constitutes abandonment. How could less care be suggested for patients undergoing a surgical procedure such as abortion.

4. An abortion can carry serious risks and complications which can be immediate and life threatening such as hemorrhagic, anesthetic and respiratory complications. Hence the need for these procedures to be carried out in a professional environment with trained staff, adequate lighting, essential equipment and sanitary conditions. In the professional setting of an ASC proper informed consent would be customary and could include information on abortion procedures, fetal development, the offering of ultrasound, alternatives to abortion, information on risks and complications of abortion including psychological consequences and the effects of abortion on the extended family. In an ASC post-op monitoring for the required time is provided and also for extended care if needed.

5. Information on medical abortion should also be made available to Patients, especially since thirty percent (30%) of all first trimester abortions are being done by medical means in the doctor's office. These abortions are usually advised for pregnancies less than seven (7) weeks, but now the envelope is being pushed to later gestational age which makes the risk of complications greater. During these procedures the patient is given the abortion pill, the most popular of these is RU486, on the first day of the abortion. This pill prevents the placenta from nurturing the embryo, which dies and sets in motion the abortion. The procedure is completed two (2) days later when the second abortion pill is given to cause contractions of the uterus to abort the fetus and placenta along with bleeding, which may last up to two (2) weeks. The same complications as with a suction abortion can occur later, such as bleeding, infection, incomplete abortion and repeat D&C to evacuate the uterus.

6. Having performed abortions myself for about five (5) years I can attest to the nature of the abortion industry. Doctors perform abortions for monetary gain. It is a lucrative cash business, a lot more lucrative nowadays than thirty (30) years ago, since demand now outweighs supply. Fewer doctors are performing abortions and abortion clinics are closing. This is not a reputable occupation for a medical professional and abortion doctors are often ostracized from mainstream medicine. So, abortion doctors have no camaraderie

with physicians in the community where they live and are itinerant from clinic to clinic within their state and sometimes travel out of state doing abortions. They never form doctor-patient relationships. This serves the patient fine because during the abortion procedure, the woman never makes eye contact with the doctor because his is a face she never wants to remember for the rest of her life. As far as the doctor is concerned she is just another cash ticket. As soon as he's done with her, it's on to the next patient and then out the door, accountable to no one.

7. Failure to implement and uphold H.B. 2 has serious and detrimental effects for women because it would (1) keep the abortion doctor unaccountable to his patient and to the community in which he practices; (2) allow him to provide women with substandard medical care which places their lives in danger; and, (3) would protect the doctor and harm the woman.

Further Affiant sayeth not."

/s/ Dr. Noreen Johnson
Dr. Noreen Johnson

SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned authority, on this 22 day of January 2016.

[SEAL]	SHERYL ANN CONNER MY COMMISSION EXPIRES June 4, 2019

/s/ Sheryl Ann Conner
NOTARY PUBLIC IN AND
FOR THE STATE OF TEXAS
Notary Public,
Brazos County Texas

My Commission Expires: 06/04/2019

APPENDIX C

Affidavit of Dr. Mayra Thompson

STATE OF TEXAS	§	KNOW ALL
	§	MEN BY THESE
COUNTY OF DALLAS	§	PRESENTS

BEFORE ME, the undersigned authority on this day personally appeared Dr. Mayra Jimenez Thompson who is personally known to me, and after being by me first duly sworn according to law on her oath did depose and say that:

1. "My name is Dr. Mayra Jimenez Thompson. I am over the age of eighteen (18) years of age and I am fully competent to make this Affidavit. I reside in Dallas, Texas. I have personal knowledge of the facts stated herein and the following is true and correct.

2. I have thirty-five years of experience in Obstetrics & Gynecology. I am board certified in obstetrics and gynecology and am a Fellow of the American Congress of Obstetricians and Gynecologists as well as a member of the Association of Advanced Laparoscopic Surgeons and American Association of Gynecologic Laparoscopists. In 2013, I was named one of the Super Doctors in Texas for Gynecology-Obstetrics and in 2015, as well as previous years, was named as one of the Best Doctors in Dallas by D Magazine.

3. I am a Professor of Obstetrics and Gynecology and teach at UT Southwestern Medical Center. I

see patients at the Lowe Foundation Center for Women's Preventative Health Care.

Management of medical elective abortion using the RU-486:

4. The FDA has approved the use of RU-486 along with misoprostol for medical induced abortion under a specific protocol and guidelines in an attempt to improve safety issues. There is a restricted use protocol which is clearly stated on the Manufacturer's website and the physician must obtain certification to prescribe the medication as well as agree to obtain a patient's written agreement as required by the FDA.

5. A qualified physician must distribute and supervise the use of the medications as delineated by this protocol.

6. The qualifications state that:

    - The doctor must have the ability to date pregnancies adequately and diagnose tubal pregnancies.
    - The doctor must be qualified to provide any necessary surgery.
    - The doctor must ensure that the women have access to medical facilities for emergency care, and must agree to other responsibilities, such as dispensing the Medication Guide and reporting adverse events.
    - The physician and the patient must sign an agreement regarding the gestational age which must be no more than 49 days and the

follow up required return office visits at day 3 and day 14 following the prescription of the RU486.

7. The importance of the 3rd day is to evaluate the patient for the addition of misoprostol which should be given in an oral form since the use of vaginal may be associated with severe infection and is the only approved method of administration.

8. These restrictions and requirements of compliance to the regimen were instituted to provide for the safety and effectiveness of the drug(s) when used in women for the purpose of medical induced abortion.

9. The FDA did not allow for off-label use of the drugs and involves a 14 day period of surveillance.

10. Considering the strict protocol delineated by the FDA, strict supervision and regulations need to be in place to guarantee the safe use of this medication.

11. The reason for strict supervision and regulations is that there is a very high risk of hemorrhage from a ruptured ectopic or tubal pregnancy which could lead to death if not recognized. It makes this a dangerous drug that must be monitored closely.

12. The risk of infection and sepsis has been reported by the FDA who stated that several of the women who died in the United States died from sepsis after medical abortion with RU-486 and misoprostol.

13. The warning signs must be recognized by all the abortion providers and they must advise the patients of the symptoms which would initiate contacting the physician.

14. The restrictions imposed by the FDA dictates that the use of RU-486 must be regulated by strict guidelines, accurate record keeping with scheduled reporting of use, complications, and distribution with serial and lot numbers. This reporting should include documentation of full informed consent as well as the patient agreement. Access to emergency care by a physician must be well established to handle the complications or risks and the patient must understand how to access the emergency care. This process should be in conjunction with the procedures the manufacturer has in place for monitoring of the drug(s).

15. The FDA did not allow for off-label use of the Mifeprex and the misoprostol for medical abortion due to the above named risks that generated the restrictions. There is to be no deviation from the protocol in order to minimize the risk of the dangers of the drug. This is meant for the safety of the patient who is to receive the drugs.

Statement regarding the number of procedures within one hour or 60 min time period:

16. In my experience, the surgical procedure involved in a suction curettage performed in the first trimester of pregnancy cannot safely be performed in less than 20 minutes actual operating time.

17. This minimum of 20 minutes does not even account for the aseptic preparation, the draping nor the pre-op analgesic/anesthetic administration.

18. Current acceptable standard of care dictates a time out with the entire team in the immediate pre-procedure time which takes anywhere from 2-10 minutes to verify procedure, medical history, allergies, and risks.

19. The safety of the patient which in this case involves a woman, cannot be guaranteed when multiple procedures performed by one doctor in one sixty minute (one hour) period of time exceeds at the very minimum, three procedures.

20. Most physicians, who perform D and C procedures in their offices (in non-pregnant patients) allow 30 to 45 minutes per procedure. A pregnant uterus poses more complex procedural requirements that could justify a longer period of time, not less.

21. The pregnant uterus is much softer and more amenable to perforation or damage and therefore has a greater risk of hemorrhage or infection. The aseptic environment in an ASC guards against these risks. Considering that the surgical abortion is a procedure with life threatening risks, appropriate surgical protocol with aseptic techniques, evaluation of medical risks, appropriate time out with the entire surgical team to ensure patient safety and access to materials in the event of a complication, these procedures are best performed in an ASC. This will also guard

against too short of a time designated per procedure to be performed.

H.B.2 provisions for ASCs and doctor privileges at local hospitals.

22. The ASC standards provide for a follow up communication with the patient to assess the post-operative condition. In the event of a suspected complication, the patient is advised on whether or not to contact her physician. The need for on-going doctor-patient care is provided for by these standards so the patient is not felt to be abandoned. The goal of this approach, the first and foremost one, is of patient safety. Access to the physician who performed the abortion for ongoing care when considering the potential complications is a must.

23. Abortion, whether surgical or medical (RU-486), has physical risks including the risk of death. This risk is at all stages of pregnancy but increases with the advancing trimesters. It also increases with subsequent abortions and/or pregnancies.

24. These physical risks include: the immediate physical complications include cervical injuries and perforated uterus; acute or chronic pain; organ or system failures cerebrovascular diseases, circulatory diseases, disseminated intravascular coagulation, amniotic fluid embolism, pulmonary embolism, and adult respiratory distress syndrome; various infections such as septic abortion, acute renal failure from septic abortion, autoimmune disease, endometritis, genital tract

infection, pelvic inflammatory disease, bacterial vaginosis.

25. Abortion can also affect later pregnancies such as infertility, ectopic pregnancy, placenta previa, subsequent miscarriages, premature birth, or law [sic] birth weight; and various cancer risks such as breast cancer.

26. The follow up communication and information on access to the physician guaranteed by the standards of the ASCs protect and benefit women when these complications arise.

27. When these complications arise, it is good for the woman to have her attending physician present and have doctor privileges at the local hospital in order to provide details of the care that may not be readily available in an emergency situation from anywhere else. Based on my medical expertise and experience, I have personally seen and heard of other physical complications that women experience from both surgical and medical abortions.

28. Based on my medical expertise and experience, I can say that the safety measures provided in H.B. 2 requiring abortions to be performed at ASCs and doctor privileges at local hospitals are reasonable and necessary for the health and safety of women considering an abortion.

Further Affiant sayeth not."

/s/ Mayra J. Thompson
Mayra J. Thompson, MD, FACOG

SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned authority, on this 21 day of January 2016.

KATHERINE SPINKS Notary Public, State of Texas [SEAL] My Commission Expires November 05, 2017	/s/ Katherine Spinks NOTARY PUBLIC IN AND FOR THE STATE OF TEXAS Notary Public, Dallas County, Texas My Commission Expires: 11-5-17